

**Atenolol Tablets (90 mg)**

Formulation: Atenolol (Stober), 93.0 g; Ludipress, 287.0 g; Kollidon CL, 52.0 g; magnesium stearate, 2.2 g; aerosil 200, 0.9 g.

**Manufacturing Directions**

Mix all components, pass through a 0.8-mm sieve, and press to tablets with low-compression force at 436 mg.

**Atorvastatin Tablets (10 mg/20 mg), Atrovastatin Calcium Lipitor**

Lipitor tablets for oral administration contain 10, 20, or 40 mg of atorvastatin and the following inactive ingredients: calcium carbonate, USP; candelilla wax, FCC; croscarmellose sodium, NF; hydroxypropyl cellulose, NF; lactose monohydrate, NF; magnesium stearate, NF; microcrystalline cellulose, NF; Opadry White YS-1-7040 (hydroxypropylmethylcellulose, polyethylene glycol, talc, titanium dioxide); polysorbate 80; and simethicone emulsion.

**Atorvastatin Calcium Tablets**

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
10.00 11.00	1	Atorvastatin, use atorvastatin calcium trihydrate	10.00 11.00
36.00	2	Calcium carbonate	36.00
65.00	3	Lactose monohydrate	65.00
30.00	4	Microcrystalline cellulose (Avicel PH 102)	30.00
3.00	5	Polyvinylpyrrolidone (Povidone K-30)	3.00
0.40	6	Polysorbate 80 (Tween 80)	0.40
4.00	7	Croscarmellose sodium (Ac-Di-Sol)	4.00
0.60	8	Magnesium stearate	0.60
—	9	Purified water	QS

**Manufacturing Directions**

- Sift atorvastatin calcium trihydrate, calcium carbonate, lactose monohydrate, and Avicel PH 102 through a 0.500-mm stainless steel sieve.
- Dissolve PVP K-30 and Polysorbate-80 in purified water (50°C) by slow stirring until it becomes clear. Cool the solution to 30°C. This is the granulating solution.
- Knead the powder mix with granulating solution to get the desired granules.
- Dry the granules to a targeted LOD of 2%.
- Pass the dried granules through #16 mesh.
- Sift Ac-Di-Sol and magnesium stearate through 0.500 mm.
- Load the ground granules from step 5 and the powder mix from step 6 into a suitable blender. Blend for 1 minute.
- Compress into 150-mg tablets, using 12-mm punches. For 20-mg strength, compress 300 mg in 15-mm punches.
- Prepare a hypromellose and polyethylene glycol 4000 solution in the mixture of purified water and ethanol 95%. Keep overnight for complete gelation. (See Appendix.)
- Add talc and titanium dioxide into step 10, and homogenize for a uniform coating dispersion.
- Coat the tablets using the coating dispersion Accel Cota to a targeted weight.